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PAPER

04/29/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,899	12/08/2000	Benjamin Chain	20555/1203433-US1	1183
7278 7590 0429/2008 DARBY & DARBY P.C. P.O. BOX 770			EXAMINER	
			SWARTZ, RODNEY P	
Church Street Station New York, NY 10008-0770			ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Application No. Applicant(s) 09/731.899 CHAIN, BENJAMIN Office Action Summary Examiner Art Unit Rodney P. Swartz, Ph.D. 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 January 2008. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-15 and 21-35 is/are pending in the application. 4a) Of the above claim(s) 13-15 and 33-35 is/are withdrawn from consideration. Claim(s) is/are allowed. 6) Claim(s) 1-5.10 and 21-25 is/are rejected. 7) Claim(s) 6-9,11,12 and 26-32 is/are objected to. 8) Claim(s) 1-15,21-35 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some \* c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date \_\_\_\_\_\_.

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

Applicant's Response to Office Action, received 23 January 2008, is acknowledged.

Claims 1 and 21 have been amended.

Claims 1-15 and 21-35 are pending. Claims 13-15 and 33-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-12 and 21-32 are under consideration.

#### **Rejections Maintained**

 The rejection of claims 1-5, 10, and 21-25 under 35 U.S.C. 102(e) as being anticipated by Perl (U.S. Pat. No. 5,879,909), is maintained.

Applicant argues that Perl does not anticipate each element set forth in the claims because Perl does not teach: 1) N as the first 2-5 amino acid residues from the free N-terminus of a ntaurally occurring internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein, and 2) C is the last 2-5 amino acid residues from the free C-terminus of a naturally occurring internal peptride cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein.

The examiner has considered applicant's argument, but does not find it persuasive. The instant claims are drawn to a peptide of formula (I) or (II) or mixtures of (I), or (II), or (I) and (II). N is designated as being 2, 3, 4, or 5 amino acids. S is a spacer amino acid residue,  $T_h$  is a T helper cell epitope, m is 0-5 and n is 1-4.

The recitation in the claims that N originates from the free N-terminus of a naturally occurring internal peptide cleavage product formed by proteolytic cleavage of a precursor protein or mature protein, or that C is the last 2-5 amino acid residues from the free C-terminus

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of a naturally occurring internal peptride cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein is merely a product by process, and does not place any patentable structure characteristic on the final product, i.e., the claimed chimeric peptide, which would differentiate the claimed peptides from peptides made by another process, such as the peptides produced by Perl.

 The objection to claims 6-12 and 26-32, being dependent from rejected claims, is maintained.

#### Conclusion

- No claims are allowed.
- 6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor. Shannon Foley. can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="https://pair-direct.uspto.gov">https://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 14, 2008



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09/731,899	CHAIN, BENJA	MIN	
Examiner	Art Unit		
Rodney P. Swartz, Ph.D.	1645		